

CHARGE: 502(f)(1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for use in the diagnosis or treatment of disease conditions, and it was not feasible to devise any directions for use because the article was worthless for any medical purposes.

DISPOSITION: 8-16-61. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

6750. Sulfonamide boluses. (F.D.C. No. 46426. S. No. 84-721 R.)

QUANTITY: 24 ctns., each containing 50 boluses, at New York, N.Y., in possession of West-Ward, Inc.

SHIPPED: 3-9-61, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: (Ctn.) "50 boluses three sulfonamides each bolus contains: sulfathiazole 80 grains sulfanilamide 80 grains sulfamethazine 80 grains warning: * * * dosage: * * * West-Ward Inc. Distributor New York, N.Y."

RESULTS OF INVESTIGATION: Analysis of the article showed that it contained essentially the declared amount of sulfonamide, and that the article did not disintegrate within a time period that would permit effective utilization of the drug for the intended purposes.

The label on the cartons had been placed there by the dealer.

LBELED: 9-6-61, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in that it did not state the conditions to be treated or the species of animals to be treated.

DISPOSITION: 10-6-61. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6751. Ferrous sulfate tablets. (F.D.C. No. 46147. S. No. 10-357 R.)

QUANTITY: 2 drums containing a total of approximately 82,000 tablets at Syracuse, N.Y.

SHIPPED: 2-8-61, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: "42000 E.C. Red Ferrous Sulfate USP Each Tablet Contains 5 Grains Ferrous Sulfate Equivalent to 1 Grain (64 mg.) of Metallic Iron * * * Lot No. 25905 Richlyn Laboratories, Philadelphia, Pa."

LBELED: 8-2-61, N. Dist. N.Y.

CHARGE: 501(b)—when shipped, the article purported to be and was represented as *ferrous sulfate tablets*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "Each Tablet Contains 5 Grains Ferrous Sulfate" was false and misleading as applied to a product containing in excess of that amount of ferrous sulfate per tablet.

DISPOSITION: 9-19-61. Default—destruction.